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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,695	10/07/2003	Vincent P. Ganion	P11193.00	6266

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EXAMINER	
FLORY, CHRISTOPHER A	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/680,695	**Applicant(s)** GANION ET AL.
	Examiner Christopher A. Flory	**Art Unit** 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-40* is/are pending in the application.

4a) Of the above claim(s) *1-12,25-30 and 36-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16,24 and 31-35* is/are rejected.

7)☒ Claim(s) *17 and 19-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, defined by claims 13-17, 19-24 and 31-35 in the reply filed on 17 April 2006 is acknowledged. The traversal is on the ground(s) that there is no undue burden imposed on the Examiner. This is not found persuasive because burden on the Examiner is established when any one or combination of the following criteria are met: the inventions have acquired a separate status in the art in view of their different classification, require a different field of search (see MPEP § 808.02), or have acquired a separate status in the art because of their recognized divergent subject matter. In this case, as per the Examiner's original argument, the inventions are subject to different classifications, with Group I directed to an implantable apparatus in class 607, subclass 9 and Group II directed to an electrical stimulation method classified in class 607, subclass 15.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-12, 25-30 and 36-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 17 April 2006.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "24 and 26" has been used to designate both the atria

and the ventricles (paragraph [38]). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: there is a typographical error in paragraph [14] that reads “includes an *electrode at* least two pacing output channels” which should be corrected to read –includes an electrode **and** at least two pacing output channels--. Appropriate correction is required.

5. The disclosure is objected to because of the following informalities: the proper application numbers for the cross-referenced applications should replace the general term “10/xxx,xxx.” They are as follows:

a. (Atty. Dkt. P-11155.00) → 10/680,528

b. (Atty. Dkt. P-11548.00) → 10/680,462

c. (Atty. Dkt. P-11354) → 10/680,494

d. (Atty. Dkt. P-11086) → 10/680,493

e. (Atty. Dkt. P-11438.00) → 10/692,990

f. (Atty. Dkt. P-11359.00) → 10/703,956

Appropriate correction is required.

Claim Objections

6. Claim 20 is objected to because of the following informalities: there is a typographical error in the second clause reading "coupling the second capacitor the first electrode" which should be corrected to read –coupling the second capacitor **to** the first electrode--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (US Patent 5,213,098, hereinafter Bennett'098).

Regarding claims 31 and 32, Bennett'098 discloses delivering pacing pulses to the heart via a first pacing output channel including a first capacitor (column 9, lines 33-57) and delivering extra-systolic pulses to the heart via a second independent pacing output channel including a second capacitor (Fig. 6; column 6, lines 38-68; column 8, lines 54-63; column 10, lines 41-62).

Regarding claim 33, an extra-systolic pulse is inherently lower in amplitude than the accompanying pacing pulse amplitude because the extra-systolic condition of the heart is a less vigorous contraction condition and has a lower threshold of stimulation. Therefore, this claim limitation of the instant application does not distinguish over the prior art, as any extra-systolic pulse delivered by an implantable system can be assumed by definition to be of a smaller magnitude than a pacing pulse delivered by that system.

9. Claims 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulligan et al. (US Patent 6,438,408).

Regarding claim 31, Mulligan et al. discloses delivering pacing pulses to the heart via a first pacing output channel (column 15, lines 22-47) and delivering extra-systolic pulses to the heart via a second pacing output channel (Column 15, lines 48-62—although this describes the same electrodes/channel, it is noted that the Mulligan et al. discloses that each channel can be programmed independently to perform any of the functions described) where the second channel is independent from the first (column 11, lines 1-15).

Regarding claim 32, Mulligan et al. does not explicitly disclose the presence of capacitors in the pacing circuitry. However, it does disclose that the system can be configured to deliver defibrillation shocks (column 6, lines 50-55; column 13, lines 15-20). Circuitry including capacitors as described in the instant application is an inherent component in any defibrillation circuit, as it is the only means by which to deliver the desired high-voltage shock. Therefore, the instant application does not structurally distinguish over the prior art presented in Mulligan et al.

Regarding claim 33, an extra-systolic pulse is inherently lower in amplitude than the accompanying pacing pulse amplitude because the extra-systolic condition of the heart is a less vigorous contraction condition and has a lower threshold of stimulation. Therefore, this claim limitation of the instant application does not distinguish over the prior art, as any extra-systolic pulse delivered by an implantable system can be assumed by definition to be of a smaller magnitude than a pacing pulse delivered by that system.

Regarding claims 34 and 35, Mulligan et al. discloses that the implantable multi-lead stimulator can incorporate cardiac resynchronization therapy as the delivered pacing (column 6, lines 50-55). By definition, cardiac resynchronization therapy must deliver pacing pulses to both ventricles of the heart in a manner that requires separate timing and therefore separate channels leading to each ventricle. Therefore, this limitation claimed in the instant application does not distinguish over the prior art.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 13-16, 24 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett'098.

Regarding claims 13 and 24, Bennett'098 discloses a method comprising coupling a first capacitor to an electrode for delivery of a first pacing pulse to the heart at a first time and coupling a second capacitor to an electrode for delivery of a second pacing pulse to the heart at a second time (Figure 2, capacitors 107, 108 coupled to lead electrodes 109, 103/105 respectively; Fig. 3 shows that the different electrodes are responsible for stimulation at different first and second times; column 8, lines 23-53), wherein the electrode is one of an electrode pair adapted to couple to one of an endocardial location (Fig. 2).

Regarding the clause that the first and second capacitor be connected only to a first electrode, Bennett'098 discloses that the device is capable of operating in a single-chamber mode, where pacing and sensing occur in only one chamber (column 9, lines 58-65). Therefore, having two channels directed to one lead electrode in that chamber is considered a functional equivalent within the art to having two channels directed to two leads within the same chamber. Although Bennett'098 shows only one capacitor being coupled to each lead electrode configuration, it is an obvious design modification to include any number of additional capacitors to deliver additional pacing shocks to each electrode, as well as to include any number of additional leads to deliver well-known types of pacing stimulation. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (The court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced).

Regarding claims 14-15 and 31-32, Bennett'098 discloses coupling the first capacitor to the heart upon expiration of an escape interval to deliver a pacing pulse (column 9, lines 33-57), and coupling the second capacitor to the heart via the electrode following expiration of an extra-systolic interval after detecting an intrinsic or paced depolarization (Fig. 6; column 6, lines 38-68; column 8, lines 54-63; column 10, lines 41-62).

Regarding claim 16, an extra-systolic pulse is inherently lower in amplitude than the accompanying pacing pulse amplitude because the extra-systolic condition of the heart is a less vigorous contraction condition and has a lower threshold of stimulation. Therefore, this claim limitation of the instant application does not distinguish over the prior art, as any extra-systolic pulse delivered by an implantable system can be assumed by definition to be of a smaller magnitude than a pacing pulse delivered by that system.

Regarding claim 34, although Bennett'098 does not explicitly disclose using the device for CRT, the patent does disclose that the device is capable of functioning in several non-rate-responsive and rate-responsive modes including being configured as a dual chamber pacing system (column 9, lines 58-65). CRT by definition is performed by a rate-responsive, dual-ventricular pacing system, and therefore the instant application does not distinguish over the prior art.

12. Claims 13-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al.

Regarding claims 13 and 24, Mulligan et al. discloses a method comprising delivering a first pacing pulse to the heart at a first time and delivering a second pacing pulse to the heart at a second time (column 15, lines 22-62; Fig. 6), wherein the electrode is one of an electrode pair adapted to couple to an endocardial location (Fig. 1). Although Mulligan et al. does not explicitly disclose the presence of capacitors in the pacing circuitry, it does disclose that the system can be configured to deliver defibrillation shocks (column 6, lines 50-55; column 13, lines 15-20). Circuitry including capacitors as described in the instant application is an inherent component in any defibrillation circuit, as a capacitor is the only means by which to safely deliver the desired high-voltage shock. Therefore, the instant application does not structurally distinguish over the prior art presented in Mulligan et al.

Regarding the clause that the first and second capacitor be connected only to a first electrode, it is an obvious design modification to include any number of additional capacitors to deliver additional pacing shocks to each electrode, as well as to include any number of additional leads to deliver well-known types of pacing stimulation.

Regarding claims 14-15, Mulligan et al. discloses coupling the first capacitor to the heart (i.e. delivering the first pacing pulse) upon expiration of an escape interval (Fig. 7, steps S704-S710; Fig. 6, steps S606-S610 and S620-S622), and coupling the second capacitor (i.e. delivering the second pacing pulse) to the heart via the electrode following expiration of an extra-systolic interval (Fig. 6, steps S614-S618) after detecting an intrinsic or paced depolarization (Fig. 6, step S602; Fig. 7, step S702).

Regarding claim 16, an extra-systolic pulse is inherently lower in amplitude than the accompanying pacing pulse amplitude because the extra-systolic condition of the heart is a less vigorous contraction condition and has a lower threshold of stimulation. Therefore, this claim limitation of the instant application does not distinguish over the prior art, as any extra-systolic pulse delivered by an implantable system can be assumed by definition to be of a smaller magnitude than a pacing pulse delivered by that system.

Allowable Subject Matter

13. Claims 17, and 19-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

George Manuel
Primary Examiner